



**Billing Code: 5001-06**

**DEPARTMENT OF DEFENSE**

Office of the Secretary

[Docket ID: DoD-2015-HA-0066]

Proposed Collection; Comment Request

**AGENCY:** Office of the Assistant Secretary of Defense for Health Affairs, DoD.

**ACTION:** Notice.

**SUMMARY:** In compliance with the *Paperwork Reduction Act of 1995*, the Office of the Assistant Secretary of Defense for Health Affairs announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

**DATES:** Consideration will be given to all comments received by [insert 60 days from publication in the Federal Register].

**ADDRESSES:** You may submit comments, identified by docket number and title, by any of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail: Department of Defense, Office of the Deputy Chief Management Officer, Directorate of Oversight and Compliance, Regulatory and Audit Matters Office, 9010 Defense Pentagon, Washington, DC 20301-9010.

*Instructions:* All submissions received must include the agency name, docket number and title for this Federal Register document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at <http://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

Any associated form(s) for this collection may be located within this same electronic docket and downloaded for review/testing. Follow the instructions at <http://www.regulations.gov> for submitting comments. Please submit comments on any given form identified by docket number, form number, and title.

**FOR FURTHER INFORMATION CONTACT:** To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Naval Health Research Center, Deployment Health Research Department, ATTN: LCDR Rachel Lee, 140 Sylvester Rd. San Diego, CA 92106-3521 or call (619) 553-8983.

**SUPPLEMENTARY INFORMATION:**

**Title; Associated Form; and OMB Number:** ACAM2000® Myopericarditis Registry; OMB Control Number 0720-0054.

**Needs and Uses:** The information collection requirement is necessary to address Food and Drug Administration requirements to establish several Phase IV post-licensure studies to evaluate the long-term safety of ACAM2000<sup>®</sup> smallpox vaccine. Among the required post-licensure studies is the establishment of a myopericarditis registry. The ACAM2000<sup>®</sup> Myopericarditis Registry is designed to study the natural history of myopericarditis following receipt of the ACAM2000<sup>®</sup> vaccine, including evaluating factors that may influence disease prognosis, thus addressing the FDA post-licensure requirement and ensuring the continued licensing of this vaccine.

**Affected Public:** Individuals or households; federal government.

**Annual Burden Hours:** 10

**Number of Respondents:** 10

**Responses per Respondent:** 2

**Average Burden per Response:** 30 minutes

**Frequency:** Semi-annually

Eligible respondents are civilians who are former Active Duty or active Guard/Reserve in the U.S. Military that received the ACAM2000<sup>®</sup> smallpox vaccine while in the military and subsequently developed signs or symptoms of myopericarditis. The information collected will illuminate the natural history of post-vaccine myopericarditis and evaluate factors that may influence disease prognosis. Inclusion of civilians who were formerly in the military in addition to current military members is imperative in order to obtain information on those who may have separated from the military due to their medical condition. Conducting this Registry will ensure the continued licensure of this military relevant vaccine.

Dated: June 25, 2015.

Aaron Siegel,

Alternate OSD Federal Register

Liaison Officer, Department of Defense

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